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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/513,888 | 02/25/2000 | Carlo M. Croce | 3589.1016-001 | 6972 |

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/513,888

Applicant(s)

CROCE ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,24 and 158-249 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23,24,158-172,200-211 and 236-249 is/are allowed.
- 6) ☒ Claim(s) 173-199 and 212-235 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 23, 24 and 158-249 are pending in the present application.

Response to Amendment

Claims 173-199 and 212-235 stand rejected under the written description requirement of 35 U.S.C. 112, first paragraph for the reasons already of record and those set forth below in reply to Applicant's arguments.

Any rejections not repeated herein are withdrawn.

Response to Arguments

Applicant's arguments filed 27 July 2005 in so far as they relate to the rejection of claims 173-199 and 212-235 under the written description requirement of 35 U.S.C. 112, first paragraph have been fully considered but they are not persuasive.

Applicant bases their arguments on the dicta in Enzo Biochem, Inc. v Gen-Probe Incorporated 232 F.3d 956 (Fed Cir 2002) ("Enzo") wherein the Court states that they are persuaded by and adopt the PTO written description guidelines. Based on this dicta from Enzo Applicant continues to conclude that the PTO written description guidelines ("Guidelines") support the position that Applicant has written description of the claimed invention.

First, the guidelines do not have the force and effect of law. Moreover, the decision in Enzo the dicta in Enzo adopting the Guidelines as guidance do not overrule precedential written description case law relating to the written description standard as it applies to nucleic acid sequences specifically as set forth in The Regents of the University of California V. Eli Lilly 119

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F.3d 1559, 43 USPQ2d 1398 (Fed cir. 1997) (“Lilly”). The holding of Lilly supports the examiners position that the claims fail to satisfy the written description requirement. A generic statement . . . without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function.” See *University of California v. Eli Lilly and co.* 119 F.3d 1559, 43 USPQ2d 1398 (1997). In the instant application, the specification fails to provide a clear structure function relationship between the fragments which hybridize to the claimed sequence and the purported function of the FEZ1 gene. Moreover, the prior art does not appear to offset the deficiencies of the instant specification with regard to a structural/functional correlation between the nucleic acids having the recited complementarity and which must also possess the recited functional activities. MPEP 2163(I)(A) clearly addresses this issue:

A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Therefore, Applicant has failed to describe any structural characteristics commonly possessed by members of the genus such that one of skill in the art would recognize that Applicant was in possession of the invention claimed.

Allowable Subject Matter

Claims 23, 24, 158-172, 200-211 and 236-249 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636



JAMES KETTER
PRIMARY EXAMINER